

No. A10-101

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STATE OF MINNESOTA  
IN SUPREME COURT

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Alan and Keri Bearder, *et al.*,

Appellants,

vs.

State of Minnesota, Department of Health,  
and Dr. Sanne Magnan, Commissioner of the Minnesota Department of Health,

Respondents.

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**RESPONDENTS' BRIEF**

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## LEGAL ISSUE

Did Respondents violate the Genetic Information Statute, Minn. Stat. § 13.386, by retaining and securely storing the minor Plaintiffs' blood specimens and newborn screening test results, absent receipt of a parental destruction directive?

*This issue was raised in Appellants' complaint and amended complaint and in the parties' competing memoranda on Respondents' motion to dismiss or, in the alternative, for summary judgment<sup>1</sup>. The district court dismissed the complaint, holding that the Genetic Information Statute does not apply to the 16 minor Plaintiffs born before the effective date of the statute, does not apply to blood specimens, and does not supersede the law governing the Newborn Screening Program. The issue was preserved for appeal by the district court's judgment entered on November 25, 2009 and by Appellants' filing of a Notice of Appeal.*

*The court of appeals affirmed the district court's judgment, holding that Newborn Screening Program activities are expressly authorized by law and thus come within an exception to the Genetic Information Statute. The court further held that Appellants' claims related to use of blood specimens outside the program failed because: (1) sixteen of the minor Plaintiffs were born before the effective date of the Genetic Information Statute, and (2) Appellants failed to present specific facts to counter Respondents' evidence "that the blood screening results of all 25 children involved in the action were not used in any public health studies or research." The issue was preserved for appeal to this Court by Appellants' filing of a petition for further review.*

*Apposite Authority:*

Minn. Stat. § 13.386 (2010)

Minn. Stat. § 13.3805 (2010)

Minn. Stat. §§ 144.125-.128 (2010)

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<sup>1</sup> See complaint, Appellants' Appendix ("AA-") at AA-269; amended complaint, AA-1; Defendants' memorandum in support of its dispositive motion on Plaintiffs' statutory claim based on Minn. Stat. § 13.386 (6/26/09); Defendants' supplemental memorandum in support of its dispositive motion to dismiss the amended complaint (8/18/09); Plaintiffs' memorandum in opposition to Defendants' motion (9/30/09); Defendants' reply memorandum (10/6/09).

## STATEMENT OF THE CASE

In March 2009, nine families<sup>2</sup> sued the State of Minnesota and the Minnesota Department of Health (“MDH”), alleging violation of Minn. Stat. § 13.386 as the result of MDH’s carrying out its duties under the Newborn Screening Program (“NBS Program”) with respect to the minor Plaintiffs. They sought relief pursuant to the “Civil Remedies” provisions of the Minnesota Government Data Practices Act (“MGDPA”), Minn. Stat. § 13.08.<sup>3</sup> Appellants amended their complaint to add the Commissioner of Health (“Commissioner”) as a defendant and to assert additional claims for damages: eight common law tort claims, two federal constitutional claims, and two state constitutional claims. Appellants subsequently withdrew claims for battery and intentional infliction of emotional distress. Respondents moved to dismiss or, in the alternative, for summary judgment. On November 24, 2009, the district court<sup>4</sup> granted the State’s motion. Judgment for the State was entered on November 25, 2009.

By Notice of Appeal dated January 13, 2010, Appellants sought review of the district court’s judgment. *See* AA-273. On August 24, 2010, the Minnesota Court of Appeals, in a published opinion, affirmed the district court’s judgment.

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<sup>2</sup> Since March 2009, one family (the Gaetano family) was added by amendment to the original complaint (*see* AA-1), and another family (the VanDemark family) was voluntarily dismissed out of the case (*see* AA-267).

<sup>3</sup> Contrary to Appellants’ statement at page 2 of their brief, neither the original complaint nor the amended complaint sought a “declaratory judgment.” *See* AA-272 (original complaint) and AA-9 (amended complaint).

<sup>4</sup> The Honorable Marilyn Brown Rosenbaum, Hennepin County, Fourth Judicial District, is the trial judge in this matter.

## STATEMENT OF FACTS

### A. Appellants.

Appellants are nine families: 17 parents (the “parent Plaintiffs”) and 25 children (the “minor Plaintiffs”). *See* Notice of Appeal, AA-273. The minor Plaintiffs were born between July 1998 and December 2008. *See* Affidavit of Matthew Zerby (“Zerby Aff.”), AA-180. Blood specimens from all 25 minor Plaintiffs were collected within the first week of life and received and tested by the NBS Program for rare and heritable congenital disorders. *See id.* As further discussed *infra* at 5, parents can direct, at the time of a child’s birth<sup>5</sup> or at any time thereafter, that MDH destroy the specimens or test results, or both. *See* Minn. Stat. §§ 144.125, subd. 3; 144.128(4) and (5). Unless a parental destruction directive was received from a parent Plaintiff, MDH retained and securely stored the specimens and test results of the minor Plaintiffs. *See* Affidavit of Mark McCann (“McCann Aff.”), AA-212.

No blood specimen from 23 of the minor Plaintiffs was used in public health studies or research. *See* Zerby Aff., AA-181. With respect to the remaining two children, MDH has no records indicating that their blood specimens were used in public health studies or research. *See id.*

Appellants object to MDH’s continued storage of any of the minor Plaintiffs’ blood specimens and test results and to the possibility that MDH would use or

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<sup>5</sup> At the time of their births, the parents of two minor Plaintiffs submitted destruction directives to MDH: one to destroy the specimen and test results of one newborn; and the other to destroy only the test results of another newborn. *See* Zerby Aff., AA-180.

disseminate the blood specimens and test results for any purpose in the future. Under Minn. Stat. § 144.128(4) and (5), all of the parent Plaintiffs have the right at any time to direct MDH to destroy their children's blood specimens and test results. Notwithstanding the availability of this simple administrative option, these parents brought this lawsuit seeking a court order to "enjoin Defendants from continuing to collect, store, use, and disseminate genetic information without informed written consent." AA-9.

**B. The Newborn Screening Program.**

MDH's NBS Program is governed by Minn. Stat. §§ 144.125-.128 (2010) and Minn. R. ch. 4615 (2009). When the program was initiated in 1965, it screened all infants born in Minnesota for phenylketonuria ("PKU"), a recessive genetic disorder that causes problems with brain development if not detected and treated early. *See McCann Aff.*, AA-210. Today, the NBS Program screens for more than 50 rare heritable and congenital disorders that, if left untreated, can lead to illness, physical disability, developmental delay or death. *See id.*; AA-218 (list of disorders). Each year, the NBS Program screens approximately 73,000 newborns, and approximately 100 are found to have a confirmed disorder. *See AA-31.*

Generally speaking, "responsible parties"<sup>6</sup> must collect or arrange for collection of a "specimen" from each newborn within five days of birth. Minn. Stat. § 144.125, subd. 1; Minn. R. 4615.0500. A few drops of blood from the infant's heel are put on a

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<sup>6</sup> "Responsible parties" include the person in charge of a hospital where the child is born and the physician in attendance at birth, or if not so attended, one of the parents. *See Minn. R. 4615.0400, subp. 5.*

filter-paper “specimen card.” See AA-219; Minn. R. 4615.0400, subp. 8. Parental consent is not required; however, parents may “opt out” of the NBS Program, in whole or in part. See Minn. Stat. § 144.125, subd. 3. “Responsible parties” must advise parents:

(1) that the *blood or tissue samples* used to perform testing thereunder as well as the results of such testing *may be retained by the Department of Health*, (2) the benefit of retaining the blood or tissue sample, and (3) that the following options are available to them with respect to the testing: (i) to decline to have the tests, or (ii) to elect to have the tests but to require that all the blood samples and records of test results be destroyed within 24 months of the testing.

*Id.* (emphasis added). A parental objection to testing or an election to require destruction of blood samples or test results must be in writing and signed by a parent or legal guardian and is part of the infant’s medical record. See *id.*

MDH’s brochure, “One simple test can make a difference to your child,” provides basic information about the NBS Program, including the fact that parents may opt out of newborn screening, and that stored leftover blood may be used for public health studies. See McCann Aff., Ex. 2, AA-217 to AA-226.

Parents or adults who were tested as minors may at any time “direct that blood samples and test results be destroyed.” Minn. Stat. § 144.128(4). MDH must “comply with a destruction request within 45 days after receiving it. *Id.* § 144.128(5). However, federal law<sup>7</sup> does not allow MDH to destroy *test results* until after a two-year period has

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<sup>7</sup> Federal law requires MDH’s laboratory to retain or be able to retrieve a copy of test reports for at least two years after the date of reporting. See 42 C.F.R. § 493.1105(a)(6) (2010).

passed. *See* McCann Aff., AA-211. Blood samples are *not* subject to the federal retention requirement and may be destroyed promptly.

Specimen cards are sent to MDH within 24 hours after collection. *See* Minn. R. 4615.0500 (D). Specimens are analyzed at MDH's laboratory and by MDH's contractor<sup>8</sup> Mayo Medical Laboratories ("Mayo").<sup>9</sup> *See* McCann Aff., AA-211. All but one of the tests are for substances in the blood. *See id.* Test results are required to be reported to the newborns' physicians. *See* Minn. Stat. § 144.128(1).

The NBS Program does not screen infant blood samples for the presence or absence of a specific DNA or RNA marker except when the "first level" test for cystic fibrosis shows an elevated level of immunoreactive trypsinogen in the blood. *See* McCann Aff., AA-212. If this occurs, MDH performs a "second level" genetic test<sup>10</sup> on the sample to see if the newborn has two copies of the genes that can lead to cystic fibrosis. *See id.*

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<sup>8</sup> Minnesota law authorizes the Commissioner to contract with any public or private entity to perform statutorily required public health services on behalf of MDH. Minn. Stat. § 144.0742.

<sup>9</sup> Generally speaking, Mayo performs certain tests using its special expertise in the use of tandem mass spectrometry and also performs certain "second level" tests. *See* McCann Aff., AA-211. Mayo's contract with MDH addresses Mayo's retention and use of blood specimens and test results. *See* AA-140-41. When Mayo receives "private data" pursuant to its contract with MDH, it is required by law to maintain the data in accordance with the statutes applicable to MDH. *See* Minn. Stat. § 13.05, subd. 6.

<sup>10</sup> No "second level" test for cystic fibrosis was performed on any of the minor Plaintiffs' blood specimens. *See* Zerby Aff., AA-180.

Unless a destruction directive has been received, MDH indefinitely stores test results<sup>11</sup> and any blood spot material that is not used up in the test. *See* McCann Aff., AA-212. The Commissioner must maintain an inventory of records (e.g., newborn screening test results in her custody) and establish the time period for retention and disposal of such records. Minn. Stat. § 138.17, subd. 7 (2010). In addition, the Commissioner is required to maintain a registry of heritable and congenital disorders detected by the NBS Program. *Id.* § 144.128(3). The data stored by MDH are classified by Minn. Stat. § 13.3805 (2010) as “private data on individuals” and handled by MDH in accordance with the statute. “Private data on individuals” are (1) not public and (2) accessible to the subject of the data. *Id.* § 13.02, subd. 12 (2010).

The Commissioner is authorized to “conduct studies and investigations, collect and analyze health and vital data, and identify and describe health problems” for the purpose of “protecting, maintaining, and improving the health of citizens.” Minn. Stat. § 144.05, subd. 1(a) (2010). As part of the NBS Program, the Commissioner of Health is authorized to periodically revise the list of newborn screening tests to “reflect advances in medical science, new and improved testing methods, or other factors that will improve the public health.” *Id.* § 144.125, subd. 2. An advisory committee to the Commissioner provides advice and recommendations concerning tests and treatments for

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<sup>11</sup> At page 6 of their brief, Appellants state that MDH “admits that Mayo is allowed to keep the testing results indefinitely.” However, this statement omits the portion of the response to Appellants’ request for admissions in which MDH stated that if a parental destruction request includes the child’s newborn screening results, Mayo destroys the test results after the two-year minimum time required by 42 C.F.R. § 493.1105(a)(6) has elapsed. *See* AA-141.

heritable and congenital disorders found in newborns. *Id.* § 144.1255. The advisory committee's activities include reviewing information on efficacy, reliability and availability of various tests and information on the severity of medical conditions caused by heritable and congenital disorders. *See id.* The advisory committee is required to discuss and assess the "benefits of performing tests for heritable and congenital disorders as compared to the costs, treatment limitations, or other potential disadvantages of requiring the tests" and also the "ethical considerations surrounding the testing, treatment, and handling of data and specimens generated by the testing requirements."

*Id.*

Infant blood samples have sometimes been utilized in public health studies,<sup>12</sup> using either "de-identified" blood samples without obtaining additional consent; or using identified blood samples after obtaining prior consent in writing from the parents. *See* McCann Aff., AA-212. A "de-identified" blood sample is a sample that is not accompanied by information that identifies the infant. *See id.*

In the past, MDH has collaborated with independent research organizations to conduct public health studies. *See id.* These projects must be reviewed and approved by MDH's Institutional Review Board ("IRB"). *See id.* In addition, independent research

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<sup>12</sup> At page 34 of their brief, Appellants mischaracterize the record when they state: "MDH admits to performing non-newborn screening related tests on over 50,000 blood samples." A review of the portion of the record cited, AA-144, shows that the State responded to a request for admission as follows: "[A]s of December 31, 2008, MDH has used more than 50,000 blood spots in studies for purpose of quality assurance, quality improvement for existing screening tests, evaluation and feasibility of new screening tests and non-newborn screening efforts in the realm of emerging health studies."

organizations must receive approval from their own IRBs in order to conduct research on human subjects. *See id.*; *see generally*, 45 C.F.R. pt. 46 (2009), Protection of Human Subjects. Under 45 C.F.R. § 46.102, informed consent from the subject is not required if the blood sample is not “individually identifiable.”

**C. Legislative Developments, 2005-2007.**

In 2005, the Legislature directed the Commissioner of Administration to review existing laws, rules, and policies to determine whether the state handles genetic information on individuals appropriately and to report to the Legislature. *See* Act of June 3, 2005, ch. 163, § 87, 2005 Minn. Laws 1877.

In January 2006, the Commissioner of Administration issued “A Report on Genetic Information and How it is Currently Treated Under Minnesota Law” (“2006 Report”). *See* Affidavit of David Orren (“Orren Aff.”), Ex. 1, AA-185. The 2006 Report identified the “current laws, regulations and guidelines used by state agencies,” including Minn. Stat. §§ 144.125 and 144.128. AA-191-97. The 2006 Report recommended the creation of a work group. *See* AA-201. The 2006 Report also recommended that the Legislature enact a definition for “genetic information,” give direction on how genetic information should be collected, stored, used and disseminated, and “*address those situations not already covered in existing law.*” *Id.* (emphasis added). The report stated: “The initial legislation should also provide other general guidance that would serve in those situations where this is not specific statutory authority.” *Id.* Although the report itself did not *recommend* a specific definition of “genetic information,” it used a “working definition” for the purposes of the study. *See* AA-190.

During the 2006 legislative session, Senate File 3132 was enacted by the Legislature and signed by the Governor. *See* Act of June 1, 2006, ch. 253, 2006 Minn. Laws 424-37 (“Chapter 253”). Sections 4, 9, and 22 of Chapter 253 are pertinent to this lawsuit.

**1. Section 4, Minn. Stat. § 13.386.**

Section 4 of Chapter 253 is codified as Minn. Stat. § 13.386 (“Section 13.386”). *See* 2006 Minn. Laws 426. Section 13.386 was effective August 1, 2006, and applies to “genetic information collected on or after that date.” *Id.*; AA-231. Its definition of “genetic information” is substantively identical to the “working definition” set forth in the 2006 Report (AA-190). Subdivision 2 classifies “genetic information” held by a government entity as “private data on individuals.” Subdivision 3 restricts the collection, storage, use and dissemination of genetic information, “unless otherwise expressly provided by law.” Under subdivision 3, genetic information may be collected and disseminated only with the written informed consent of the individual, may be used only for purposes to which the individual has given written informed consent, and may be stored only for a period to which the individual has given written informed consent. Because it requires individual consent, this statutory scheme may be fairly characterized as an “opt in” scheme.

During the discussion of Senate File 3132 on the House Floor, a question was posed to the author, Representative Holberg, concerning Section 13.386, as follows:

Representative Lieblich Thank you. Representative Holberg, I just have to ask you, the section that’s in here on genetic information is that going to impact the Mayo Clinic’s ability to do

medical research, collect samples, and use it years later to cure diseases that we didn't even know we had? I just wonder if you have been through the process with them and had hearings that in which you learned a little bit about how that might impact medical research in this state? . . . I am talking about Section 4 of the DE2 amendment . . .

Representative Mr. Speaker and Representative Liebling, this governs the  
Holberg collection of data by government entities and does not preclude that collection if it's otherwise allowed by current law. This was a recommendation of the genetic information study group. . . .

*See* Affidavit of Pamala Hughes ("Hughes Aff."), Ex. 4, AA-261.

**2. Section 9, Amendments to the Newborn Screening Statute.**

Section 9 of Chapter 253 amends the NBS Program statute to add three new requirements: (1) preparation of a form for use by parents or by adults who were tested as minors to direct that blood samples and test results be destroyed; (2) compliance with a destruction request within 45 days of receipt; and (3) notification to the individuals that request destruction of samples and test results that the samples and test results have been destroyed. *See* Minn. Stat. § 144.128(4)-(6); 2006 Minn. Laws 429, AA-233.

**3. Section 22, Creation of a Work Group.**

Section 22 of Chapter 253 required the creation of a work group "to develop principles for public policy on the use of genetic information." 2006 Minn. Laws 436, AA-238. The law required the work group to report to the Legislature concerning "options for resolving questions of secondary uses of genetic information" and "retention schedules for genetic information held by government entities." AA-238, AA-239.

In January 2009, a report entitled “Genetic Information in Minnesota” was issued. *See* Orren Aff., AA-183 and Ex. 2, AA-206. The report contains recommendations for future legislative consideration and a statement that “[t]here is a need for additional guidance from the Legislature regarding Minnesota Statutes, section 13.386.” *Id.* However, the 2009 Legislature did not amend Section 13.386. Orren Aff., AA-183.

**D. Rulemaking Proceedings To Amend The Newborn Screening Rules.**

In December 2005, MDH began the process to amend the newborn screening rules in order to bring them up to date with 2003 statutory amendments and technological advances and to clarify the roles of MDH, hospitals and other health care providers. Orren Aff., AA-183. The proposed rules were published in the State Register. 42 *State Register* 663 (Nov. 20, 2006). In January 2007, a rulemaking hearing was held before an Administrative Law Judge (“ALJ”). Orren Aff., AA-184. The ALJ, *sua sponte*, raised the issue of whether Section 13.386 applies to the NBS Program. *See* March 23, 2007 ALJ Report, Finding 64, AA-37. The ALJ concluded that existing law expressly authorizes MDH and responsible parties to initially collect “genetic information” without written informed consent but does not expressly authorize storing or disseminating it without written informed consent required by Section 13.386. *See id.*, Finding 65. As a result, the ALJ found a defect in the rules and suggested ways to correct the defect. *See id.*, Finding 67, AA-38. The ALJ recommended adopting the proposed rules, “except where noted otherwise.” *See* AA-52.

On March 27, 2007, the Chief ALJ affirmed the ALJ’s report in all respects. Orren Aff., AA-184. The Commissioner requested the Chief ALJ to reconsider the ALJ’s

defect findings. *Id.* On July 3, 2007, the Chief ALJ denied the request. *Id.* MDH chose not to adopt the proposed rules. *Id.*

**E. District Court And Court Of Appeals' Proceedings Concerning Section 13.386.**

In their Complaint and First Amended Complaint, Appellants alleged that as a result of Respondents carrying out their duties and responsibilities under the NBS Program, Respondents violated Section 13.386 with respect to the minor Plaintiffs. *See* AA-5, AA-269-72. Appellants sought injunctive and other relief pursuant to Minn. Stat. § 13.08. Respondents moved for dismissal or, in the alternative, for summary judgment.

Judge Marilyn Rosenbaum granted Respondents' motion. *See* Appellants' Addendum ("Add.") at 63. In her decision, Judge Rosenbaum noted: "Plaintiffs admit that the initial taking of samples under the NBS Program is lawful, but argue that the retention, use, and/or dissemination of the blood samples after collection and/or the reporting of positive results to physicians for follow-up care is unlawful." *Id.* at 72. Judge Rosenbaum ruled that Section 13.386 was inapplicable to the 16 minor Plaintiffs who were born before the August 1, 2006 effective date of the statute. Judge Rosenbaum ruled that MDH did not violate Section 13.386 with respect to the remaining nine minor Plaintiffs because: (1) biological (blood) specimens are not "genetic information" within the definition of Section 13.386, but that (2) even if specimens are genetic information, Section 13.386 "does not supersede specific existing law such as the NBS Program, Minn. Stat. §[§] 144.125-.128." Add. at 72.

On appeal, the Minnesota Court of Appeals affirmed the district court's judgment on the grounds that Minn. Stat. §§ 144.125-.128 and other applicable law granting MDH broad authority to manage the NBS Program amount to "express" provisions of law that authorize collection, retention, use and dissemination of blood specimens for the NBS Program, making Section 13.386 inapplicable to newborn screening-related activities. In addition, the court ruled that: (1) Section 13.386 did not apply to the 16 minor Plaintiffs whose birth dates preceded the August 1, 2006 effective date of Section 13.386, and (2) as to the remaining nine minor Plaintiffs, Appellants failed to offer any evidence to counter the Respondents' evidence "that the blood screening results of all 25 children involved in the action were not used in any public health studies or research." Add. at 60.

## ARGUMENT

### I. STANDARD OF REVIEW.

The district court granted the State's motion to dismiss or, in the alternative, for summary judgment. A motion to dismiss for failure to state a claim is treated as a motion for summary judgment "if matters outside the pleadings are presented to and not excluded by the court." Minn. R. Civ. P. 12.02. Because the district court considered affidavits and other evidence submitted by the parties, this Court's review is under a summary judgment standard. *See Fabio v. Bellomo*, 504 N.W.2d 758, 761 (Minn. 1993).

Summary judgment is proper when there is no genuine issue of material fact and "either party is entitled to a judgment as a matter of law." Minn. R. Civ. P. 56.03; *see DLH, Inc. v. Russ*, 566 N.W.2d 60, 69 (Minn. 1997). When a motion for summary judgment is made, the nonmoving party may not rest on mere averments or denials but

must present specific facts showing there is a genuine issue for trial. Minn. R. Civ. P. 56.05. The nonmoving party must “present more than evidence ‘which merely creates a metaphysical doubt as to a factual issue.’” *Valspar Refinish, Inc. v. Gaylord’s, Inc.*, 764 N.W.2d 359, 364 (Minn. 2009) (quoting *DLH, Inc.*, 566 N.W.2d at 71).

The applicable standard of review on a grant of summary judgment is *de novo*. See *Minn. Voyageur Houseboats, Inc. v. Las Vegas Marine Supply, Inc.*, 708 N.W.2d 521, 524 (Minn. 2006). The *de novo* standard applies to questions of law, including statutory interpretation. See *Houston v. Int’l Data Transfer Corp.*, 645 N.W.2d 144, 149 (Minn. 2002).

## **II. THE STATE DID NOT VIOLATE SECTION 13.386.**

Appellants claim that the State, through its NBS Program, violated Section 13.386 with respect to the 25 minor Plaintiffs by retaining their blood specimens and newborn screening test results after initial screening<sup>13</sup> was complete and, allegedly, disseminating their blood samples and/or test results for use in public health studies or research. Appellants’ claim has no merit. First, the State did not and could not have violated Section 13.386 with respect to infant blood samples because Section 13.386 does not define “genetic information” to include biological samples. Second, the State did not and could not have violated Section 13.386 because the State’s conduct with respect to the

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<sup>13</sup> Appellants do not claim that the “informed written consent” requirements of Section 13.386 apply to the NBS Program’s initial collection of infant blood specimens and testing of the specimens. See, e.g., App. Br. at 1, 22. Rather, they claim that Section 13.386 governs storage, use or dissemination of blood specimens and test results *beyond the initial newborn screening* for heritable and congenital disorders. See *id.*

minor Plaintiffs' information after initial screening falls within the "otherwise expressly provided by law" exception of Section 13.386. Third, the State did not and could not have violated Section 13.386 with respect to the 16 minor Plaintiffs whose blood specimens were collected and tested prior to Section 13.386's effective date. Finally, even if Section 13.386 applied to the NBS Program, the State did not violate it with respect to "dissemination" of the minor Plaintiffs' genetic information because no such dissemination occurred. Because there was no violation of Section 13.386 with respect to Appellants, Appellants are not entitled to relief under Minn. Stat. § 13.08.

**A. Section 13.386 Does Not Apply To Infant Blood Specimens Because Section 13.386 Does Not Define "Genetic Information" To Include Biological Samples.**

The State did not and could not have violated Section 13.386 with respect to the minor Plaintiffs' blood specimens because Section 13.386 does not define "genetic information" to include biological samples.<sup>14</sup> The statute provides:

(a) "Genetic information" means *information* about an *identifiable individual* derived from the presence, absence, alteration, or mutation of a gene, or the presence or absence of a specific DNA or RNA marker, which has been *obtained from an analysis of*:

- (1) the individual's *biological information or specimen*; or

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<sup>14</sup> The district court ruled: "Blood samples taken pursuant to the NBS Program are biological samples, not genetic information as defined in [Section 13.386]." Add. at 72. The court of appeals disagreed, ruling that blood samples fall within the definition of "genetic information" in subdivision 1(b) of Section 13.386 because they are "medical or biological information collected from an individual about a particular genetic condition that is or might be used to provide medical care to that individual." Add. at 60. These rulings pertain to interpretation of a statute, which is subject to de novo review by this Court. *Larson v. State*, 790 N.W.2d 700, 703 (Minn. 2010).

(2) the biological information or specimen of a person to whom the individual is related.

(b) “Genetic information” also means medical or biological information collected from an individual about a particular genetic condition that is or might be used to provide medical care to that individual or the individual's family members.

Minn. Stat. § 13.386, subd. 1 (emphasis added). Under this definition, genetic information is “information” about an “identifiable individual” that is “*obtained from an analysis of*” the individual’s “biological information or specimen.” *Id.* (emphasis added). Thus, a biological specimen may be the *source* of genetic information, but it is not itself genetic information.<sup>15</sup>

The language of Section 13.386 treats a “biological specimen” as separate from “genetic information” and separate from “biological information.” This treatment reflects the Legislature’s recognition that a biological specimen is a physical object rather than “data.” Section 13.386 is part of the MGDPA, Minn. Stat. ch. 13. The Legislature’s decision not to include a physical object in the definition of “genetic information” is consistent with the fact that physical objects (other than information media such as audio

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<sup>15</sup> Appellants contend that because the court of appeals’ ruling on this issue was adverse to the State and the State did not seek cross-review of the ruling pursuant to Minn. R. Civ. App. P. 117, subd. 4, the State is precluded from making this argument on appeal. *See App. Br.* at 18. However, this Court recently stated: “We have continued to rely on the principle . . . ‘that a respondent may, without taking a cross-appeal, urge in support of a decree any matter appearing in the record, even though the argument may involve an attack upon the reasoning of the lower court or an insistence upon matters overlooked or ignored by it.’” *Day Masonry v. Indep. Sch. Dist.* 347, 781 N.W.2d 321, 331 (Minn. 2010) (quoting *Hunt by Hunt v. Sherman*, 345 N.W.2d 750, 753 n.3 (Minn. 1984)). Because the applicability of Section 13.386 to biological specimens has been fully argued in the trial court and the court of appeals, this Court’s consideration of the issue is appropriate.

and/or visual recordings, computer discs, etc.) are not “data”<sup>16</sup> within the meaning of the MGDPA.

The MGDPA regulates the collection, creation, storage, maintenance, dissemination and access to “government data” by government entities. *See* Minn. Stat. § 13.01, subd. 3 (2010). The purpose of the MGDPA is “to balance the rights of data subjects from having information indiscriminately disclosed with the right of the public to know what the government is doing.” *Int’l Bhd. of Elec. Workers v. City of St. Cloud*, 765 N.W.2d 64, 66 (Minn. 2009). “Although the term ‘data’ is not defined in the MGDPA, ‘data’ usually is said to mean ‘individual facts, statistics, or items of information.’” *Westrom v. Minn. Dep’t of Labor & Indus.*, 686 N.W.2d 27, 34 (Minn. 2004) (quoting *The Random House Dictionary of the English Language* 508 (2d ed. 1987)). Where the MGDPA provides an opportunity to inspect, it states that inspection “includes, but is not limited to, the visual inspection of paper and similar types of government data.” Minn. Stat. § 13.03, subd. 3(b) (2010). Further, under the MGDPA, state agencies are frequently required to provide “copies” of government “data.” *See id.* § 13.03, subd. 3. It would be a physical impossibility for the State to “copy” a physical object<sup>17</sup> such as a blood specimen. Therefore, it is consistent with the overall

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<sup>16</sup> Although Section 13.386 uses the term “information” instead of “data,” the two terms are similar enough to be interchangeable within the context of the MGDPA. The dictionary definition of “information” refers to “knowledge,” e.g., “knowledge derived from study, experience, or instruction.” *The American Heritage Dictionary* 660 (2d College ed. 1985).

<sup>17</sup> Case law pertaining to the interpretation of the term “records” in the federal Freedom of Information Act, 5 U.S.C. § 552 (“FOIA”) indicates that the archival exhibits consisting

structure of the MGDPA for the Legislature not to include biological specimens in the definition of “genetic information” but rather to limit that term to information obtained from analysis of biological specimens.

Appellants urge the Court to adopt the court of appeals’ ruling that blood specimens fall within the definition of subdivision 1(b) of Section 13.386, which includes “medical or biological information collected from an individual about a particular genetic condition that is or might be used to provide medical care to that individual or the individual's family members.” This interpretation ignores the Legislature’s specific use of different terms in the statute. Subdivision 1(a) of the statute clearly makes a distinction between “biological information” and a “biological specimen,” and thus the two terms were not intended to have the same meaning. Subdivision 1(b) does not refer to biological specimens at all. It refers to medical or biological *information* but not to any physical object. As stated above, physical objects are not “information” or “data” but rather things from which facts, statistics, or other items of information may be derived from study or examination.

Given the placement of Section 13.386 within the MGDPA and given the distinction between “data” or “information” and a physical object, it is clear that the Legislature did not include blood samples within the definition of “genetic information.”

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of a rifle, bullets, and clothing pertaining to the assassination of President Kennedy are not “records” under FOIA. *See Nichols v. United States*, 325 F. Supp. 130, 135-36 (D. Kan. 1971), *aff’d on other grounds*, 460 F.2d 671 (10th Cir. 1972).

**B. The State's Conduct With Respect To The Minor Plaintiffs' Genetic Information After Initial Screening Comes Within The "Otherwise Expressly Provided By Law" Exception To Section 13.386.**

The State did not and could not have violated Section 13.386 with respect to the minor Plaintiffs' genetic information because the NBS program's retention of genetic information (i.e., test results), absent a parental destruction directive, falls within the "otherwise expressly provided by law" exception to Section 13.386. As shown by its legislative history, Section 13.386 was not intended by the Legislature to displace or override other statutory schemes governing programs that involve collection of genetic information. Appellants' reliance on the March 2007 ALJ Report ruling on the legality of proposed amendments to the newborn screening rules is misplaced. Those proceedings are neither relevant nor binding on the Court.

**1. The State's retention of the minor Plaintiffs' test results after initial newborn screening comes within the "otherwise expressly provided by law" exception to Section 13.386.**

Appellants' claim that Respondents violated Section 13.386, subd. 3, after the initial screening of the minor Plaintiffs was complete because Respondents did not obtain informed written consent for any post-screening retention or dissemination of the minor Plaintiffs' genetic information. Subdivision 3 of Section 13.386, entitled "Collection, storage, use and dissemination of genetic information," provides:

*Unless otherwise expressly provided by law, genetic information about an individual:*

(1) may be collected by a government entity, as defined in section 13.02, subdivision 7a, or any other person only with the written informed consent of the individual;

(2) may be used only for purposes to which the individual has given written informed consent;

(3) may be stored only for a period of time to which the individual has given written informed consent; and

(4) may be disseminated only:

(i) with the individual's written informed consent; or

(ii) if necessary in order to accomplish purposes described by clause (2). A consent to disseminate genetic information under item (i) must be signed and dated. Unless otherwise provided by law, such a consent is valid for one year or for a lesser period specified in the consent.

(Emphasis added.) The clear language<sup>18</sup> of Section 13.386 indicates that its limitations on collection, storage, use and dissemination of genetic information do not apply in cases where there is another applicable law that expressly governs collection, storage, use or dissemination of genetic information in a particular setting.

The record in this case shows that MDH: (1) received and tested the minor Plaintiffs' blood specimens within the first week of life, and (2) unless a parental destruction directive was received, securely stored the specimens and test results,<sup>19</sup> all in accordance with Minn. Stat. §§ 144.125 and 144.128.<sup>20</sup> The statutory scheme embodied

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<sup>18</sup> If the language of a statute is clear, the statute should be interpreted as consistently as possible with the purpose of the act. *See Stansell v. City of Northfield*, 618 N.W.2d 814, 819-20 (Minn. Ct. App. 2000).

<sup>19</sup> *See Zerby Aff.*, AA-180; *McCann Aff.*, AA-212.

<sup>20</sup> There is nothing in the record to indicate that Respondents disseminated the minor Plaintiffs' genetic information, and thus no evidence to support any violation of Section 13.386 based on dissemination. The minor Plaintiffs' newborn screening test results are classified as "private data on individuals" pursuant to Minn. Stat. § 13.3805. Under Section 13.386, subd. 2, genetic information held by a government entity is also classified as "private data on individuals."

in Minn. Stat. §§ 144.125-.128 is an “opt out” scheme. Appellants do not challenge the legality of MDH’s initial collection and testing of the blood samples<sup>21</sup> under the “opt out” scheme and thus apparently concede that these actions come within the “expressly otherwise provided by law” exception of Section 13.386. However, they claim that, although Minn. Stat. §§ 144.125-.128 *implies* that MDH may retain blood samples and test results after initial testing, the exception to Section 13.386 is not applicable in this case because the law does not otherwise *expressly* provide for such post-screening retention. *See* App. Br. at 24. This argument has no merit.

Subdivision 3(3) of Section 13.386 provides that “genetic information about an individual . . . may be stored only for a period of time to which the individual has given written informed consent.” A logical interpretation of this language is that the person storing the information must destroy it or otherwise get rid of it at the end of the “period of time to which the individual has given informed consent.” The statute governing the NBS Program expressly provides otherwise. Minnesota Statutes section 144.128(5) requires MDH to “comply with a destruction request within 45 days of receiving it.” The logical interpretation of this statute is that MDH may retain the information<sup>22</sup> until 45 days after receiving a destruction directive. This interpretation is supported by the fact that “responsible parties” are required by Minn. Stat. § 144.125, subd. 3, to inform

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<sup>21</sup> As stated *supra*, the minor Plaintiffs’ blood samples are not “genetic information” within the meaning of Section 13.386, subd. 1.

<sup>22</sup> The destruction requirement of Minn. Stat. § 144.128(5) applies equally to blood specimens retained in the NBS Program. However, as discussed *supra*, blood specimens are not “genetic data” within the meaning of subdivision 1 of Section 13.386.

parents “that blood or tissue samples used to perform testing thereunder as well as the results of such testing may be retained by the Department of Health” and also to inform parents of “the benefit of retaining the blood or tissue sample.”

The object of all construction of statutes is to “ascertain and effectuate the intention of the legislature.” Minn. Stat. § 645.16 (2010). Statutes should be construed, whenever possible, to give effect to all their provisions. *See Am. Family Ins. Grp. v. Schroedl*, 616 N.W.2d 273, 277 (Minn. 2000). The legislative intent reflected in the notification provision of section 144.125 could not be more clear: MDH has discretion to retain blood samples and test results after initial screening is complete. If MDH does *not* have this discretion, then the requirement to notify parents that samples and test results “may be retained” by MDH would have an absurd result: it would impose a legal requirement upon responsible parties to provide parents with false information. The Legislature “does not intend a result that is absurd . . . or unreasonable.” Minn. Stat. § 645.17(1) (2010). Thus, MDH’s retention of post-screening test results comes within the “otherwise expressly provided by law” exception of Section 13.386. MDH’s conduct did not violate Section 13.386.

2. **The contemporaneous legislative history of Section 13.386 and the circumstances under which it was enacted show that it was not intended to displace or override other statutory schemes that govern collection, storage, use or dissemination of genetic information in a particular setting.**

Because the language of Section 13.386 is clear, resort to legislative history is unnecessary in this case. *See* Minn. Stat. § 645.16(7) (court may consider contemporaneous legislative history *only if* the words of the law are not explicit).

However, to the extent the Court finds the language of Section 13.386 to be unclear, examination of the contemporaneous legislative history and the circumstances under which the statute was enacted is appropriate. *See id.* § 645.16(2), (7). The legislative history of Chapter 253 shows that Section 13.386's limitations on collection, storage, use and dissemination of genetic information were meant to cover situations not covered by other applicable laws, and that the Legislature did not intend for Section 13.386 to change or supplant the existing newborn screening laws.

The genesis of Section 13.386 was the 2006 Report, which recommended that the Legislature give direction on the handling of genetic information and also "*address those situations not already covered in existing law.*" Orren Aff., Ex. 1, AA-201 (emphasis added). The 2006 Report further recommended that the initial legislation provide guidance to serve "in those situations where there is not specific statutory authority." These recommendations are reflected by the inclusion of the "unless expressly provided by law" language. Indeed, on the House floor, the author, Representative Holberg, stated that Section 13.386 "governs the collection of data by government entities and does not preclude the collection if it's otherwise allowed by current law." Hughes Aff., Ex. 4, AA-261.

The legislative history demonstrates that the Legislature did not intend for Section 13.386 to displace or override existing newborn screening laws. Section 9 of Chapter 253 amended Minn. Stat. § 144.128 to add three new requirements: (1) prepare a separate form for use by parents or adults who were tested as minors to direct that blood samples and test results be destroyed; (2) comply with a destruction request within

45 days after receiving it; and (3) notify individuals who request destruction and test results that the samples and test results have been destroyed. *See* 2006 Minn. Laws 429. The 2006 additions to the newborn screening statute regarding destruction requests reflects the Legislature's intent to retain the "opt out" nature of the NBS Program and not to supersede it with the "opt in" statutory scheme of Section 13.386, which, for example, in subdivision 3(3), allows storage of information "only for a period of time to which the individual has given written informed consent." In enacting Chapter 253, the Legislature could have altered the "opt out" statutory scheme embodied in Minn. Stat. § 144.125 or imposed additional consent requirements to the NBS Program, but it did not. Because the Legislature clearly did not intend to disturb existing laws relating to the NBS Program, Section 13.386 does not apply to the program.

Appellants argue that Section 13.386 and the statutes governing the NBS Program can both be applied, without conflict,<sup>23</sup> to the NBS Program by (1) dividing up the NBS Program into an "initial screening" phase and a "post-initial screening" phase; (2) applying the "opt out" statutory scheme to the "initial screening" phase, consisting of collecting and testing blood samples; and (3) applying the "opt in" statutory scheme to "post-initial screening" phase, consisting of any retention or dissemination of blood samples or test results following initial screening. However, the facts of this case do not require the Court to reach that question because the Respondents' conduct with respect to

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<sup>23</sup> "A statute is to be construed, *whenever reasonably possible*, in such a way as to avoid irreconcilable differences and conflict with another statute." *Miller v. Colortyme, Inc.*, 518 N.W.2d 544, 551 (Minn. 1994) (emphasis added).

the minor Plaintiffs was within the “expressly provided by law” exception set forth in Section 13.386, i.e., collection of a blood sample, testing, and, in the absence of a parental destruction request, retaining the sample and test results.<sup>24</sup> See Minn. Stat. §§ 144.125, 144.128, 13.3805. Moreover, there is no need to harmonize Section 13.386 with the statutes governing the NBS Program because this is not a situation where both statutory schemes apply to the same program. Because the NBS Program’s handling of the minor Plaintiffs’ blood samples and test results is governed by express provisions of law, Section 13.386 does not apply and does not conflict with NBS Program statutes.

Appellants argue that the consequence of rejecting their proposed interpretation of Section 13.386 is to render the statute “meaningless.” App. Br. at 30-31. This argument has no merit. Section 13.386 was enacted to “address those situations not already covered in existing law,” Orren Aff., Ex. 1, AA-201, and is fully applicable to situations where the collection of genetic information is not governed by another applicable law. Rejection of the Appellants’ argument does not nullify Section 13.386.

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<sup>24</sup> Under the facts of this case, the issue of the use of the minor Plaintiffs’ blood specimens in public health research is not before this Court because, as discussed *infra* at 31-33, there is no evidence in the record indicating that the minor Plaintiffs’ blood specimens were used in public health research. However, even if Section 13.386 applied to public health research associated with the NBS Program in the manner Appellants assert, the record shows that the utilization of infant blood specimens in public health research is consistent with Section 13.386. Under Section 13.386, subd. 1(a), which pertains to information obtained from the analysis of a biological specimen, “genetic information” is “information about an identifiable individual.” Prior written consent from parents is obtained for use of infant blood samples in public health studies if the samples are to be accompanied by information that identifies individuals. See McCann Aff., AA-212.

**3. The “legislative and administrative interpretations” relied upon by Appellants do not support their proposed interpretation of Section 13.386.**

Citing to Minn. Stat. § 645.16(8),<sup>25</sup> Appellants argue that the legislative intent underlying Section 13.386 can be ascertained by considering legislative and administrative interpretations of Section 13.386. However, the legislative and administrative materials upon which Appellants rely provide no guidance to the Court regarding legislative intent.

First, the “legislative interpretations” upon which Appellants rely to support their interpretation of Section 13.386 are transcripts of a March 16, 2009 Senate hearing and a March 27, 2009, House hearing on a bill that did not pass. These hearings occurred three years after passage of Section 13.386. Specifically, Appellants rely on statements made by one senator and two members of the House indicating their “understanding” of the application Section 13.386 to the NBS Program. *See* App. Br. at 27, 28. Outside the context of *contemporaneous* legislative history, in which legislative hearing transcripts are sometimes considered by the courts in determining legislative intent,<sup>26</sup> there is no authority to support the proposition that statements of individual legislators made during

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<sup>25</sup> “When the words of a law are not explicit, the intention of the legislature may be ascertained by considering, among other matters: . . . (8) legislative and administrative interpretations of the statute.”

<sup>26</sup> *See Handle With Care, Inc. v. Dep’t of Human Servs.*, 406 N.W.2d 518, 522 (Minn. 1987) (in considering contemporaneous legislative history, Court has on occasion considered transcripts of recordings of committee meetings and floor debates; statements made in committee discussion or floor debate are to be treated with caution; statements made by the sponsor of a bill or amendment on the purpose or effect of the legislation are generally entitled to some weight).

debate on a bill are relevant in determining legislative intent. The term “legislative interpretations” as used in Minn. Stat. § 645.16(8) has been applied to statutory amendments specifically intended to “clarify, rather than to change” the statutes amended<sup>27</sup> and to a formal report to a legislative commission concerning two legislative proposals that led to statutory amendments.<sup>28</sup> The 2009 comments from legislators are neither contemporaneous legislative history<sup>29</sup> nor “legislative interpretations” concerning Section 13.386 and shed no light on the statutory interpretation issue before this Court.

Second, to support their interpretation of Section 13.386, Appellants rely upon the 2007 rulings of the ALJ and Chief ALJ in connection with proposed amendments to the newborn screening rules, Minn. R. ch. 4615.<sup>30</sup> See App. Br. at 28-30. However, under the circumstances of this case, the rulings of the Office of Administrative Hearings (“OAH”) in a rulemaking proceeding are not entitled to any deference in determining the legislative intent behind Section 13.386.

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<sup>27</sup> See *City of Red Wing v. Ellsworth Cmty. Sch. Dist.*, 617 N.W.2d 602, 608-09 (Minn. Ct. App. 2000) (interpreting the Municipal Tort Claims Act).

<sup>28</sup> See *In re Masson*, 753 N.W.2d 755, 760 (Minn. Ct. App. 2008) (considering expression of intent contained in report to the Minnesota Legislative Commission on Pensions and Retirement).

<sup>29</sup> Section 13.386 was enacted in 2006. Statements of legislators subsequent to the passage of an act of the legislature cannot be used to infer the intent of the legislature. *Haage v. Steies*, 555 N.W.2d 7, 9 (Minn. Ct. App. 1996) (1995 affidavit of co-author and sponsor of bill was not contemporaneous legislative history of bill enacted in 1984); *Laue v. Prod. Credit Ass'n*, 390 N.W.2d 823, 828 (Minn. 1986) (statements made by legislators after passage of act are not contemporaneous legislative history).

<sup>30</sup> In the district court, Appellants relied heavily on these rulings as “proof” that Respondents violated Section 13.386. The district court properly found the ALJ proceedings to be “not relevant” and “not binding on the court.” Add.-72.

Administrative interpretations of an ambiguous statute are entitled to deference in ascertaining legislative intent when two elements are present: (1) where the question presented involves the application of expertise in the intricacies of administering a particular program or implementing a particular statute, and (2) where the administrative interpretation is of long standing. *See Brayton v. Pawlenty*, 781 N.W.2d 357, 366 n.4 (Minn. 2010). Neither element is involved here.

First, OAH is a state agency. Minn. Stat. § 14.48 (2010). It is not the state agency charged with administering the NBS Program or any other program that requires expertise concerning the handling of “genetic information” and thus cannot be said to have special expertise on the subject matter. OAH conducts rulemaking hearings for other state agencies. The adoption of rules is a legislative-type function. *See Eagle Lake of Becker Cnty. Lake Ass’n v. Becker Cnty. Bd. of Comm’rs*, 738 N.W.2d 788, 793-94 (Minn. Ct. App. 2007). After the ALJ and the Chief ALJ agreed that the rules had a defect, MDH had a choice: either to correct the “defect” or withdraw the rules. *See* Minn. Stat. § 14.16, subd. 2 (2010). When MDH withdrew the proposed rules, the rulemaking proceeding was complete. Outside the context of the rulemaking proceeding, the OAH’s ruling is not binding on MDH.<sup>31</sup>

Second, the OAH’s interpretation was not accepted or implemented by MDH and cannot be considered a “longstanding” interpretation of the statute. *See In re Answer of*

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<sup>31</sup> Indisputably, the OAH’s ruling is not binding on the courts. Minn. Const. art. VI vests the judicial power of the state in the courts. ALJ jurisdiction is “inferior to the district court’s jurisdiction.” *Holmberg v. Holmberg*, 588 N.W.2d 720, 726 (Minn. 1999). This Court is fully empowered to interpret Section 13.386.

*Minn. Power & Light Co.* 182 N.W.2d 685, 689 (Minn. 1970) (commission's ruling that was challenged "almost immediately" was not longstanding statutory interpretation). Therefore, the OAH's ruling of MDH's proposed rules are not entitled to deference in this proceeding.

Even if OAH's adverse ruling on the proposed rules were to be considered, it is not persuasive. The ALJ did not take into account the legislative history indicating the legislative intent that Section 13.386 cover situations involving the handling of genetic information not already addressed by existing law. In addition, the ALJ interpreted the term "genetic information" to include biological specimens. *See* ALJ Report, Findings 63-67, AA-36 to AA-39. As further discussed below, under the definition in Section 13.386 "genetic information" does not include biological specimens.

**C. The State Could Not Have Violated Section 13.386 With Respect To The 16 Minor Plaintiffs Whose Blood Specimens Were Collected And Tested Prior To The Statute's Effective Date.**

Section 4 of Chapter 253 provides the following effective date for Section 13.386:

**EFFECTIVE DATE.** This section is effective August 1, 2006, and applies to genetic information *collected on or after that date.*

AA-231 (emphasis added). Even if Section 13.386 applied to the NBS Program in general, it did not apply to genetic information that was collected prior to the August 1, 2006 effective date of Section 13.386. The minor Plaintiffs' blood specimens were collected within the first week of life. *See* Zerby Aff., AA-180. A review of the birth dates of 16 minor Plaintiffs (*see id.*, initials R.H., B.H., A.G., H.G., M.K., M.B., N.G., K.B, G.H., M.V., J.G., W.H., J.N., C.K., J.B. and L.H.) shows that these children were

born before August 1, 2006. Because Section 13.386 does not apply to these children, the State could not have violated the statute as to them.

Appellants argue that notwithstanding the effective date of Section 13.386, the State must obtain written informed consent in order to store, use or disseminate blood specimens and test results obtained before August 1, 2006. Appellants' interpretation is erroneous. First, a blood specimen that falls outside of the definition of "genetic information" is not governed by Section 13.386. Second, application of the law to genetic information collected *prior to* August 1, 2006, would give the statute retroactive effect. "No law shall be construed to be retroactive unless clearly and manifestly so intended by the legislature." Minn. Stat. § 645.21 (2010). A statute is afforded retroactive application only if there is clear evidence that the Legislature intended it to be retroactive, such as using the word "retroactive." *See In re Estate of Edhlund*, 444 N.W.2d 861, 862 (Minn. Ct. App. 1989). The "effective date" language used by the Legislature for Section 13.386 is unambiguous and reflects no intent to apply the law retroactively.

**D. Even If Section 13.386 Applies To The NBS Program, MDH Did Not "Disseminate" The Minor Plaintiffs' Genetic Information.**

Appellants alleged that the State violated Section 13.386 by "disseminating" their blood specimens to outside organizations for research. Even if the Court should find that Section 13.386 applies to the NBS Program, this claim lacks merit.

As discussed *supra*, blood specimens are not "genetic information." Appellants' claims based on "dissemination" of blood specimens fail. But even if blood specimens

are “genetic information,” the State was entitled to summary judgment. The evidence in the record indicates that no blood specimen from any of 23 of the minor Plaintiffs was used in public health research. *See Zerby Aff.*, AA-181. MDH has no records indicating that the specimens of the remaining two minor Plaintiffs were used in public health studies or research. *See id.* Appellants’ claim that MDH violated 13.386 by improper dissemination or use of the minor Plaintiffs’ blood specimens fails for lack of factual support.<sup>32</sup>

Appellants presented no evidence to counter the State’s evidence. Thus, Appellants failed to “present specific facts showing there is a genuine issue for trial,” as required by Minn. R. Civ. P. 56.05, to support their claim that the State violated Section 13.386 by disseminating their genetic information. A material fact issue must be established by “substantial evidence.” *Murphy v. Country House, Inc.*, 240 N.W.2d 507, 512 (Minn. 1976). General assertions and promises to produce evidence at trial do not to create a genuine issue of material fact for trial. *See Nicollet Restoration, Inc. v. City of St. Paul*, 533 N.W.2d 845, 848 (Minn. 1995). Mere speculation, in the absence of some concrete evidence, is insufficient to avoid summary judgment. *See Osborne v. Twin*

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<sup>32</sup> Notwithstanding the utter lack of evidence that the State used the minor Plaintiffs’ blood specimens in *any* public health studies, the court of appeals, in dicta, stated that “any use of specimens for purposes not related to the newborn screening program is subject to the written informed consent requirements of the genetic privacy act.” Add. at 60. The role of an appellate court is to decide actual controversies and avoid advisory opinions predicated on hypothetical facts. *See Pechovnik v. Pechovnik*, 765 N.W.2d 94, 97 (Minn. Ct. App. 2009). There is no party before this Court whose blood specimen was used for purposes not related to the newborn screening program. It was improper for the court of appeals to render an interpretation of Section 13.386 with respect to hypothetical facts.

*Town Bowl, Inc.*, 749 N.W.2d 367, 371 (Minn. 2008). Due to the lack of any evidence to counter the State’s evidence on “dissemination” of genetic information, the district court’s grant of summary judgment was proper.

**E. Appellants Are Not Entitled To Relief.**

Appellants are not entitled to relief under the “Civil Remedies” provisions of the MGDPA, Minn. Stat. § 13.08. That statute provides for a damages remedy for a violation of the MGDPA, for injunctive relief for violation or proposed violation, and for an action to compel compliance with the MGDPA. *See* Minn. Stat. § 13.08, subds. 1, 2, 4. Because Section 13.386 has no application to the Appellants, there has been no violation or “proposed” violation on the part of Respondents to support Appellants’ claims for relief. Even if Section 13.386 applied, Respondents have taken no action with respect to Appellants that is not expressly authorized by the laws governing the NBS Program.

At pages 31-35 of their brief, Appellants appear to argue that even if 16 of the minor Plaintiffs were born before the effective date of Section 13.386, and even if there is no evidence that Respondents disseminated their genetic information, they are nevertheless entitled to “declaratory relief” under Minn. Stat. § 13.08 regarding their “rights” under Section 13.386. This argument has no merit. On its face, section 13.08 is aimed at enforcement of the MGDPA, and the remedies it affords are specific; they do not include declaratory relief.<sup>33</sup> More importantly, however, the issue of declaratory

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<sup>33</sup> *Compare* Minn. Stat. § 13.08 and Minnesota’s declaratory judgment statute, Minn. Stat. § 555.01 (2010): “Courts of record within their respective jurisdictions shall have power to declare rights, status, and other legal relations *whether or not further relief is or could be claimed.*” (Emphasis added.)

relief is not properly before this Court. Appellants did not ask for declaratory judgment in their complaint or in their amended complaint, nor was the issue raised or litigated in either the district court or the court of appeals. See A-272, AA-9. *Thiele v. Stich*, 425 N.W.2d 580, 582 (Minn. 1988) (stating that this Court generally will not consider matters not argued and considered in the district court). Thus, the Court should decline to consider this issue.

Even if the Court considers Appellants' declaratory judgment argument, Appellants cannot prevail on their claim. In a declaratory judgment action, the plaintiff must be "possessed of a judicially protectible right or status" which is "in jeopardy." *Minneapolis Fed'n of Men Teachers v. Bd. of Educ.*, 56 N.W.2d 203, 205 (Minn. 1952). Appellants seek to enforce alleged "rights" that are a creation of statutes. Appellants can only have a claim of "rights" under Minn. Stat. § 13.08 if the Appellant has shown that (1) Section 13.386 applies to Appellants, and (2) Respondents violated it with respect to Appellants. Because Appellants have met neither of these conditions, Appellants have no "rights" that can be "declared" under Minn. Stat. § 13.08.

Appellants' assertion that they are entitled to injunctive relief must be viewed in light of the fact that injunctive relief is an equitable remedy. See *Borom v. City of St. Paul*, 184 N.W.2d 595, 598 (Minn. 1971). The courts' equitable powers "may not be invoked to grant injunctive relief where there is an adequate remedy at law." *Id.* Appellants' claim for injunctive relief is based primarily on the "threat" that Respondents will, in the future, use the minor Plaintiffs' genetic information in an "ongoing program of dissemination and research." App. Br. at 34. However, without the need for any

intervention by any court, Appellants are fully empowered to prevent Respondents from further retaining, for any and all purposes, any of the minor Plaintiffs' blood specimens and test results, simply by providing a written destruction directive to MDH. *See* Minn. Stat. § 144.128(4) and (5). The availability of this simple administrative remedy shows that even if Appellants could prevail in any manner on the merits of their MGDPA claim, their claim for injunctive relief is groundless.

**CONCLUSION**

Because no material fact dispute exists and the court of appeals did not err in affirming the district court's grant of summary judgment, the State respectfully requests that the Court affirm the court of appeals' decision.

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Respectfully submitted,

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